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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,852	09/22/2000	Per Johan Lundberg	1103326-0686	1116

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/646,852	LUNDBERG ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-18,20 and 23-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-18,20 and 23-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Response to Non-Final Office Action filed 10/18/04.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 6-18, 20 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nara et al. US 6,245,351.

Nara teaches a controlled release composition comprising a drug-containing core coated with a coating composition containing a water-insoluble substance and a swellable polymer (abstract, column1, lines 50-63). Drugs include omeprazole and lansoprazole, are mixed with excipient, such as sucrose or calcium phosphate (osmotic agent); binder; disintegrant, such as , sodium crosslinked carboxymethylcellulose or

low-substitutional hydroxypropyl cellulose (swelling agent); and lubricant, including talc (alkaline additive) (column 3, lines 59-61; column 5, lines 36-52; and examples). Core can be in the form of granule, fine granule, or inert carrier particles include sucrose (column 5, lines 30-35, and 60-65). The water-insoluble substance contained in the coating composition includes ethyl cellulose, cellulose acetate, and Eudragit RS (column 4, lines 5-25; and column 6, lines 15-25). The coating composition further comprises talc (modifying agent) (column 6, lines 50-55; and example 3). The examples show the weight of coating composition is about 20-30% to the core. The coated core can be prepared in tablet or capsule form for oral administration (column 6, lines 56-65; and claim 7).

It is noted that Nara does not explicitly teach the weight ratio of the modifying agent to water-insoluble substance, as well as the amount of the alkaline additive and swelling agent in the core. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine suitable amount of talc in the core composition as well as in the coating composition, because Nara teaches the release rate of the active ingredient is mainly in the small and large intestine without an enteric coating, while the release rate of the active ingredient is very limited in the stomach

(column 1, lines 53-55; and column 7, lines 25-31), and because Nara teaches a coated formulation with low toxicity that can be safely used in human. The expected result would be a controlled-release composition comprising omeprazole in the core without enteric coating that can limit release of omeprazole in the stomach, but increases release in the small and large intestine.

Claims 4, 5 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nara et al. US 6,245,351, in view of Cotton et al. WO 98/54171.

Nara is relied upon for the reason stated above. Nara is deficient in the fact that it does not specifically teach magnesium salt of omeprazole.

Cotton teaches novel form of S-enantiomer of omeprazole, including S-omeprazole, and more specifically, magnesium salt of S-omeprazole trihydrate (hereafter, the compound) (see abstract, and page 1, lines 4-10). Cotton also teaches the compound is formulated into oral dosage form, *e.g.*, capsule, tablet, and the like (page 6, lines 15-30). The formulation is effective as a gastric acid secretion inhibitor and is useful as an anti-ulcer agent (page 6, lines 1-14).

Cotton does not explicitly teaches the compound having a crystallinity of more than 70%, however, Cotton teaches that the compound of his invention is highly crystalline, *i.e.*, having a higher crystallinity than any other form of magnesium salt of S-omeprazole in the prior art (page 3, lines 24 through page 4, lines 1-7). Therefore, the burden is shifted to applicant to show the compound taught by Cotton does not have the crystallinity being claimed. It is also noted that Cotton teaches the trihydrate form, *e.g.*,

magnesium salt of S-omeprazole "trihydrate". However, applicant claims recite a generic form of magnesium salt of S-omeprazole with the transitional phrase "comprising of" permits any other form, including "trihydrate" taught by Cotton. Thus, it would have been obvious for one of ordinary skill in the art to modify the controlled release composition comprising a drug-containing core coated with a *non-enteric* coating composition using the magnesium salt of S-omeprazole trihydrate in view of the teaching of Cotton, because Cotton teaches the compound of his invention is more stable, easier to handle and store, easier to synthesize in a reproducible manner, because Cotton teaches the compound is most preferred in oral administration formulation, because Nara teaches a non-enteric coated formulation with low toxicity that can be safely used in human. The expected result would be a controlled-release composition comprising omeprazole in the core without enteric coating that can limit release of omeprazole in the stomach, but increases release in the small and large intestine.

Response to Arguments

Applicant's arguments filed 10/18/04 have been fully considered but they are not persuasive.

Applicant argues that Nara teaches the swellable agent or polymer is in the coating composition, not in the core as claimed. Contrary to the applicant's argument, applicant's attention is called to column 5, lines 25-52; and examples, where Nara teaches the drug-containing core is prepared by mixing the drug with an appropriate

excipient, binder, disintegrant, lubricant etc., wherein binder includes a low-substitutional hydroxypropyl cellulose (swelling agent); and lubricant includes talc (alkaline additive). Accordingly, Nara does teach the swellable agent or polymer is in the core as being claimed.

Applicant argues that Nara teaches the coating contains a hydrophilic substance and the swellable agent, both of which are excluded from the semipermeable membrane by the use of the transitional phrase "consisting essentially of". Contrary to the applicant's argument, Nara clearly states that the use of the hydrophilic substance is optional (see column 6, line 20), and the coating composition contains one of the water-insoluble substance, or swellable polymer (see column 20, lines 18-19). Furthermore, it is noted that *absent a clear indication in the specification or claims of what the basic and novel characteristics actually are*, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG; 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also > AK Steel Corp. v. Sollac, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003) (Applicant's statement in the specification that "silicon contents in the coating metal should not exceed about 0.5% by weight" along with a discussion of the deleterious effects of silicon provided basis to conclude that silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention. Thus, "consisting essentially of" as recited in the preamble was interpreted to permit no

more than 0.5% by weight of silicon in the aluminum coating.);< In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989). Applicant's specification at page 8 discloses the membrane comprises a water insoluble polymer and a modifying additive and excipients like fillers, colorants etc. The excipients should be insoluble or hardly soluble in acidic solutions. Additionally, applicant's example 2 shows the use of unrecited ingredients, such as cross-linked polyvinyl pyrrolidone, or hydroxypropylcellulose L. applicant's attention is also called to Nara at column 1, lines 61-62; and column 14, lines 4-5, where Nara teaches the release rate starts in the small intestine as desired by the applicant.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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